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EXAMINER

LUDLOW, JAN M

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,606

Applicant(s)

HUNNELL ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 18, 20-22 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 16, 19, 23-28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 5, 11-15, 17-18, 20, 22, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al ('197) in view of Louder et al ('312).

Kinney et al ('197) teaches a processing (retort) chamber 12; wax baths 13, 14; reagent containers 15; fluid transport system 38, 33, 42, 62, 63, including rotary valve

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39 and additional valves 75, 75'; five heaters 84, 89, 91, 77, 77 for heating the wax baths, processing chamber as well as part of the fluid transport system (valves 75, 75' and conduits 62, 63, see, e.g., col. 6, lines 1-13), a pressure/vacuum pump 60, and controller 100. The housing holding the reagent and wax containers constitutes the instant chambers. The controller is preferably solid-state logic circuitry (col. 7, line 24). Signal lights indicate which solution is being pumped (col. 8, lines 29-31). Cycles of vacuum and air pressure are applied to the wax to release air bubbles (col. 7, lines 33-60). Fumes are filtered prior to release (see element 69).

Kinney fails to teach computer control.

Louder teaches a system similar to that of Kinney, under computer control (col. 4, line 23). A purge port is provided for cleaning (col. 2, line 64)

It would have been obvious to one of ordinary skill in the art to use a computer as the solid state logic circuit in Kinney in order to control a processing bath system as taught by Louder. It would have been obvious to provide a port in the valve coupled to purge so as to be able to clean the system as taught by Louder. It would have been obvious to make the containers of any known inert material, such as plastic, with known connectors for their known connection function. The computer controller manages the reagents, including indicating which are pumped and operator input sets the program, defining (limiting) the use of reagents.

5. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney and Louder as applied to claim 5 above, and further in view of Pickett.

Kinney and Louder fail to teach a "Maltese cross" gear in the rotary valve.

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Pickett teaches a rotary valve suitable for use in the device of Kinney (col., 2, line 31). The valve includes a disc with detents (col. 4, line 2) for registering the valve ports. A switch including a sensor is also provided (col. 5, lines 60-65). It is the examiner's position that the disc with detents constitutes a Maltese cross gear. See, e.g., Van Riemsdijk.

It would have been obvious to use the valve of Pickett in the device of Kinney because Pickett explicitly teaches to do so.

6. Claims 1, 2, 5, 11-15, 17-18, 20, 22, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshiyama ('943) in view of Louder et al ('312).

Yoshiyama teaches a processing chamber 15, reagent chambers 4-5, with containers 7a, 7b, resin (wax) chamber 6 with container 7c, fluid transport system with rotary valve 9, pumps 13 and 22, and heaters for the processing chamber and wax container. Filters 21 and 24 are provided. Vacuum inherently draws air bubbles from the wax.

Yoshiyama fails to teach heaters for the fluid transport system or a computer controller.

Louder teaches a system similar to that of Yoshiyama, under computer control (col. 4, line 23). A purge port is provided for cleaning (col. 2, line 64) and a heater is provided for the valve block 28 and wax lines (Fig. 1).

It would have been obvious to provide a computer controller to the apparatus of Yoshiyama in order to automate processing as taught by Louder. It would have been

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further obvious to provide heaters for the fluid transport system as taught by Louder in order to keep the wax warm and/or molten during transport.

7. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshiyama and Louder as applied to claims 1-2 above, and further in view of Schmehl.

8. The primary references fail to teach plastic bottles and quick connects.

9. Schmehl teaches a system similar to that of Yoshiyama and Louder. Reagents are provided in plastic bottles with quick connections (bridge cols. 4-5).

10. It would have been obvious to provide the reagents of Yoshiyama in quick connect plastic bottles as taught by Schmehl in order to contain the reagents in inert, break-resistant, easily changed containers. In that the wax of Yoshiyama is shown in a bottle similar to that of the reagents, it would have been obvious to provide the wax in the same type of bottle as the reagents.

11. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshiyama and Louder as applied to claim 5 above, and further in view of Pickett.

Yoshiyama and Louder fail to teach a "Maltese cross" gear in the rotary valve.

Pickett teaches a rotary valve suitable for use in a tissue processing apparatus.

The valve includes a disc with detents (col. 4, line 2) for registering the valve ports. A switch including a sensor is also provided (col. 5, lines 60-65). It is the examiner's position that the disc with detents constitutes a Maltese cross gear. See, e.g., Van Riemsdijk.

It would have been obvious to use the valve of Pickett in the device of Yoshiyama because Pickett teaches that the valve is suitable for use in such a device.

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12. Claims 18, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al ('197) in view of Louder et al ('312) as applied to claim 1 above, and further in view of Rasmussen and/or Petschek.

The primary references fail to teach indicating when reagents are used and require replacement.

Rasmussen teaches an automated laboratory device using reagents. Sensors indicate when a reagent is used up and requires replacement and the operator is signaled to make the replacement (col. 1, lines 37-57).

Petschek teaches an automated laboratory device using reagents. Sensors indicate when a reagent is used up and requires replacement and the operator is signaled to make the replacement (col. 5, lines 4-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an indication of reagent use and replacement needs in the controller of the primary references in order to automate reagent management as taught by Rasmussen and/or Petschek in an automated laboratory device.

13. Claims 18, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshiyama in view of Louder et al ('312) as applied to claim 1 above, and further in view of Rasmussen and/or Petschek.

The primary references fail to teach indicating when reagents are used and require replacement.

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Rasmussen teaches an automated laboratory device using reagents. Sensors indicate when a reagent is used up and requires replacement and the operator is signaled to make the replacement (col. 1, lines 37-57).

Petschek teaches an automated laboratory device using reagents. Sensors indicate when a reagent is used up and requires replacement and the operator is signaled to make the replacement (col. 5, lines 4-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an indication of reagent use and replacement needs in the controller of the primary references in order to automate reagent management as taught by Rasmussen and/or Petschek in an automated laboratory device.

14. Claims 16, 19, 23-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to teach or suggest a tissue processing device as claimed including heaters positioned as claimed or controller operative as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml